EU Legislative and Policy Developments in the Medicinal Products area

EU28: SCIENCE MEDICINES HEALTH, A REGULATORY SYSTEM FIT FOR THE FUTURE

Dubrovnik, Croatia, 6-7 May 2013

Mr Stefano Soro, Head of Unit

Medicinal products: quality, safety and efficacy

Directorate General for Health and Consumers

Health and Consumers

Outline

- ✓ **Pharmacovigilance legislation**
- ✓ **Fees for Pharmacovigilance**
- ✓ **PRAC – Black symbol – PAES**
- ✓ **Joint Action on Pharmacovigilance**
- ✓ **International: Reform of ICH and Regulatory Cooperation**
- ✓ **Commission Reports**
- ✓ **Falsified medicines legislation**
- ✓ **Clinical trials**

Pharmacovigilance legislation

- ✓ **New pharmacovigilance legislation**:
  - ❑ Applicable since July 2012
- ✓ **Targeted amendment**:
  - ❑ Applicable from June 2013 (Regulation 2012/1027) and October 2013 (Directive 2012/26/EU)
- ✓ **Implementation by Member States**:
  - ❑ Several Member States have not yet (fully) implemented the 2010 legislation
- ✓ **Commission measures:**
  - ❑ Legal proposal for fees for pharmacovigilance (ordinary legislative procedure)
  - ❑ Black symbol
  - ❑ Post-Authorisation Efficacy studies

Black symbol - PAES

- ✓ **Black symbol (▼)**

  Commission Implementing Regulation (EU) No 198/2013

  - For products already on the market, the Regulation provides phasing-in arrangements
  - EMA published the list for additional monitoring: 25 April 2013

- ✓ **Post-Authorisation Efficacy Studies:**

  Commission had a public consultation and will continue dialogue with experts from Member States on the content of the delegated act on situations where those studies are necessary

Introduction of fees for Pharmacovigilance
Public consultation

- ✓ The **public consultation** of the Commission's **Concept Paper** that was based on EMA estimations was concluded on 15 September 2012

- ✓ The Commission has published a **summary of the replies** to the public consultation

Introduction of fees for Pharmacovigilance
Next steps: *Legislative process*

- ✓ The Commission is finalising the **Impact Assessment** with different options. This is a prerequisite before putting forward a legal proposal (foreseen in summer 2013)

- ✓ Legislative process: ordinary legislative procedure ('co-decision' by the Council and the European Parliament)

DG SANCO proposal for Joint Action on Pharmacovigilance (2013 – 2016)

✓ *Aim:*

- Support Member States to find solutions for organising and running their pharmacovigilance system in the context of the new pharmacovigilance legislation in the EU

✓ *Current status:*

- UK is coordinating project proposal
- 24 Member States, Croatia and Iceland are included as partners in the submitted project proposal

✓ *Next:*

- Project proposal has been submitted and the evaluation committee will take place in June

International
Reform of ICH and Regulatory Cooperation

✓ ***International Conference on Harmonisation***:

- Agreement has been reached on the new governance (clarifying role of industry v. regulators)
- Work continues on defining criteria for membership (global outreach) and on improving the functioning of the ICH (legal entity, financing…) as well as on enhancing transparency

✓ ***Regulatory Cooperation***:

- Reform of the Regulators Forum: a promising venue for Regulatory Cooperation with our Strategic Partners

Commission Reports in preparation

- ✓ 5-year report on the Paediatric Regulation
  - Public Consultation concluded
- ✓ Report on the Advanced Therapy Regulation
  - Public Consultation concluded
- ✓ Report on readability of product information PIL/SmPCs
- ✓ Study on environmental effects of medicines
  - Study by contractor due to be finalised in 2013
  - Development of a strategy for the pollution of water by pharmaceutical substances

Commission Reports in preparation

✓ *Report on personalised medicine*

- **Aim of the report**
  - Potential and issues in the use of –omics technologies in research and development of personalised medicine - Horizon 2020;
  - Recent developments of EU legislation to ensure the placing on the market of medicinal products and medical devices;
  - Factors affecting the uptake of personalised medicine in healthcare systems - HTA.
- **Pharmaceutcial Committee consulted**
- **Report planned for second half 2013**

Falsified Medicines

EU Directive adopted in June 2011 - Transposition by January 2013

***Implementing measures**:*

- ✓ *Revised guidelines for good distribution practices for medicinal product for human use*

  → *Published in the Official Journal.*

- ✓ *Delegated act on the detailed rules for a unique identifier for medicinal products, and its verification =>*

  → *Impact assessment on-going and delegated act in 2014.*

- ✓ *Delegated act on principles and guidelines of GMP for active substances in the EU:*

  → *Consultation of MS experts concluded. Adoption still planned for 2013.*

- ✓ *Delegated act on the introduction of medicines (import for export)*

  → *on hold.*

- ✓ *Establishment of a common EU logo for online pharmacies. Implementing act to be prepared by the end of 2013.*

Falsified Medicines

Importation of active substances (Date of application: July 2013)

- ✓ Contacts with third countries still on-going at technical and political level to *guarantee a smooth implementation* of the upcoming rules.
- ✓ Switzerland has been listed. Australia will be listed on 25 April. US, Japan and Brazil are on-going. We hope to conclude US and Japan before July 2013.
- ✓ India and China will issue written confirmation
- ✓ Mexico, Russia, Turkey, South Africa, and South Korea will also issue 'written confirmation'.

Clinical Trials

- ✓ In Council IRL Presidency plans to do a 'read-through' of all articles under their Presidency.
- ✓ In EP, IMCO, INTRE and LIBE committees voted. ENVI (Lead Committee) plans to vote at the end of May.

Thank you!

European Commission

Public Health information:

http://ec.europa.eu/health/index_en.htm